

§ 895.22 Submission of data and information by the manufacturer, distributor, or importer.

(a) A manufacturer, distributor, or importer of a device may be required to submit to the Food and Drug Administration all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. The data and information required by the Commissioner may include scientific or test data, reports, records, or other information, including data and information on whether the device is safe and effective for its intended use or when used as directed, whether the device performs according to the claims made for the device, and information on adulteration or misbranding. Any relevant information that is voluntarily submitted will also be reviewed.

(b) A manufacturer, distributor, or importer of a device required to submit data and information as provided in paragraph (a) of this section will be notified in writing by the Food and Drug Administration that such data and information shall be submitted. The written notification will advise the manufacturer, distributor, or importer of the device that the purpose for the request is to enable the Commissioner to determine whether any of the conditions listed in paragraph (a) of this section or § 895.30(a)(1) exists with respect to the device such that a proceeding should be initiated to make the device a banned device. When the required data and information can be identified by the Food and Drug Administration at the time of the notification, the agency will provide such identification to the manufacturer, distributor, or importer of the device.

(c) The required data and information shall be submitted to the Food and Drug Administration no more than 30 days after the date of receipt of the request, unless the Commissioner determines that the data and information shall be submitted by some other date and so informs the manufacturer, distributor, or importer, in which case the data and information shall be sub-

mitted on the date specified by the Commissioner.

(d) If the data or information submitted to the Food and Drug Administration is sufficient to persuade the Commissioner that the deception or risk of illness or injury or the danger to the health of individuals presented by a device could be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a restricted device, the Commissioner will proceed in accordance with § 895.25.

(e) If the data or information submitted to the Food and Drug Administration is insufficient to show that the device does not present a substantial deception or an unreasonable and substantial risk of illness or injury, or an unreasonable, direct, and substantial danger to the health of individuals, or if the manufacturer, distributor, or importer fails to submit the required information, the Commissioner may rely upon this insufficiency or failure to submit the required information in considering whether to initiate a proceeding to make the device a banned device under § 895.21(d) and, when appropriate, to establish a special effective date in accordance with § 895.30. The Commissioner may also initiate other regulatory action as provided in the act or this chapter.

§ 895.25 Labeling.

(a) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device specifying:

(1) The deception or risk of illness or injury or the danger to the health of individuals,

(2) The labeling or change in labeling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and

(3) The period of time within which the labeling, change in labeling, or change in advertising must be accomplished.

(b) In specifying the labeling or change in labeling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to include in labeling for the device, and in advertising if the device is a restricted device, a statement, notice, or warning. Such statement, notice, or warning shall be in the manner and form prescribed by the Commissioner and shall identify the deception or risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals associated with the device as previously labeled. Such statement, notice, or warning shall be used in the labeling and advertising of the device for a time period specified by the Commissioner on the basis of the degree of deception, risk of illness or injury, or danger to health; the frequency of sale of the device; the length of time the device has been on the market; the intended uses of the device; the method of its use; and any other factors that the Commissioner considers pertinent.

(c) The Commissioner will allow a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device a reasonable time, considering the deception or risk of illness or injury or the danger to the health of individuals presented by the device, within which to accomplish the required labeling, change in labeling, and, if the device is a restricted device, any change in advertising. The Commissioner may, however, request that no additional devices be introduced into commerce until the labeling or change in labeling, or change in advertising is accomplished by the manufacturer, distributor, importer, or other person(s) responsible for the labeling or advertising of the device.

(d) If such voluntary action is not taken, the Commissioner may take action under other sections of the act to

prevent the introduction of the devices into commerce. The Commissioner may consider the failure of a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to accomplish the required labeling or change in labeling, or change in advertising in accordance with this section as a basis for initiating a proceeding to make a device a banned device in accordance with § 895.21(d) and when appropriate to establish a special effective date in accordance with § 895.30.

§ 895.30 Special effective date.

(a) The Commissioner may declare a proposed regulation under § 895.21(d) to be effective upon its publication in the FEDERAL REGISTER and until the effective date of any final action taken respecting the regulation if:

(1) The Commissioner determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with use of the device that is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and

(2) Before the date of the publication of such regulation, the Commissioner notifies the domestic manufacturer and importer, if any, of the device that the regulation is to be made so effective. If necessary, the Commissioner may also notify the distributor or any other responsible person(s). In addition, the Commissioner will attempt to notify any foreign manufacturer when the name and address of the foreign manufacturer are readily available.

(b) This procedure may be used when the Commissioner determines that the potential or actual injury involved is a serious one that the Commissioner believes will endanger the health of individuals who have been, or will be, exposed to the device. In assessing the degree of danger, the Commissioner need not find that the danger is immediate, and it shall be sufficient for the Commissioner to determine that the danger may involve a serious long-term risk.

(c) If the Commissioner makes a proposed regulation effective in accordance with this section, the Commissioner will, as expeditiously as possible, give interested persons prompt